

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Ivan C. KING and Li Mou ZHENG
U.S. Serial No. : 10/738,423
Confirmation No. : 8783
Filed : December 16, 2003
Art Unit : 1633
Examiner : Qian Janice LI
For : COMPOSITIONS AND METHODS FOR TUMOR-TARGETED
DELIVERY OF EFFECTOR MOLECULES

Law Offices of Albert Wai-Kit Chan, LLC
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May 24, 2007

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir/Madam:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, Applicant(s) would like to direct the Examiner's attention to the references listed in forms PTO/SB/08A and PTO/SB/08B attached herein as **Exhibit A**.

Applicants would like to note that the listed references were submitted on April 18, 2007 in related U.S. Serial No. 11/627,743, filed January 26, 2007. Accordingly, pursuant to 37 CFR 1.98(d), a copy of these references is not required to be submitted with this SIDS. However, Applicants invite the Examiner to contact the Applicants' undersigned attorney's office if a copy of any of the listed references is desired.

Applicants : Ivan C. KING and Li Mou ZHENG
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1. U.S. Patent No. 6,475,482, November 5, 2002, Bermudes, et al., "Genetically Modified Tumor-Targeted Bacteria With Reduced Virulence" (Applicants' Dkt #871-AZ-US)
2. U.S. Patent No. 5,318,900, June 7, 1994, Habuka, et al., "method for Producing Antiviral Protein utilizing E.Coli Transformant and Gene and E.Coli Vector Used in the method"
3. U.S. Patent No. 6,923,972, June 2, 2005, Bermudes, et al., "Methods for Use Of Genetically Modified Tumor-Targeted Bacteria With Reduced Virulence" (Applicants' Dkt #871-AZA-US)
4. U.S. Patent No. 5,830,702, November 3, 1998, Portnoy, et al., "Live, Recombinant Listeria Monocytogenes Vaccines and Production of Cytotoxic T-Cell Response"
5. U.S. Patent No. 6,051,237, April 18, 2000, Paterson, Yvone "Specific Immunotherapy of Cancer Using a Live Recombinant Bacterial Vaccine Vector"
6. U.S. Patent No. 6,863,894, March 8, 2005, Bermudes, et al., "Genetically Modified Tumor-Targeted Bacteria with Reduced Virulence" (Applicants' Dkt #871-BA-US)
7. U.S. Patent No. 6,447,784, September 10, 2002, Bermudes, et al., "Genetically Modified Tumor-Targeted Bacteria with Reduced Virulence" (Applicants' Dkt #871-B-US)

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11. Supplemental Partial European Search Report for Vion Pharmaceuticals, Inc., European App'l No. 00957764.1, Filed May 3, 2002, Dated October 10, 2005
12. European Patent No. EP 0322237, June 28, 1989, The Wellcome Foundation Ltd., "Vaccines"
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15. European Patent No. EP 0285152, March 30, 1988, Birkman, et al., "Recombinant DNA for the Repressive and Inducible Expression of Heterogeneous Genes"

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20. Japanese Patent No. JP06046890, February 22, 1994, Karapetyan, Anaito "Method for Initial Diagnosis of Cancer"
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22. International Publication No. WO/1992/015689, September 17, 1992, Charles, et al., "Expression of Recombinant Proteins in Attenuated Bacteria"
23. International Publication No. WO/1999/013053, March 18, 1999, Bermudes, et al., "Genetically Modified Tumor-Targeted Bacteria With Reduced Virulence"
24. European Search Report issued on May 13, 2005 for VION Pharmaceuticals, Inc., European App'l No. EP 98946891.3

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If a telephone interview would be of assistance in advancing the prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below. If any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

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Exhibit A

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1

of 6

Complete if Known

Application Number	10/738,423
Filing Date	December 16, 2003
First Named Inventor	KING, et al.
Art Unit	1633
Examiner Name	Qian Janice L.
Attorney Docket Number	873-Z-US

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1	US- 6,475,482	11-05-2002	Bermudes, et al.	
	2	US- 5,318,900	06-07-1994	Habuka, et al.	
	3	US- 6,923,972	06-02-2005	Bermudes, et al.	
	4	US- 5,830,702	11-03-1998	Portnoy, et al.	
	5	US- 6,051,237	04-18-2000	Paterson, Yvone	
	6	US- 6,863,894	03-08-2005	Bermudes, et al.	
	7	US- 6,447,784	09-10-2002	Bermudes, et al.	
	8	US- 6,685,935	02-03-2004	Pawelek, et al.	
	9	US- 2005-0249709 A1	11-10-2005	Bermudes, et al.	
	10	US- 2003-0059400 A1	03-27-2003	Szalay, et al.	
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FOREIGN PATENT DOCUMENTS

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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	12	EP 0322237	06-28-1989	Welcome Foundation, Ltd		
	13	EP 0400958	12-02-1990	Dougan, et al.		
	14	EP 0357208	03-07-1990	Sadoff, et al.		
	15	EP 0285152	03-30-1988	Birkman, et al.		
	16	EP 0338679	10-25-1989	Sherwin, Stephen A.		
	17	EP 0564121	10-06-1993	Karapetyan, Anait		

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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		Country Code ² Number ³ Kind Code ² (if known)				
	18	EP 00195672	09-24-1986	Matsuhiro, Aizo		
	19	WO/1997/008955	03-13-1997	Branstrom, et al.		
	20	JP 06046890	02-22-1994	Karapetyan, Anaito		
	21	WO/1995/05835	03-02-1995	Woo, et al.		
	22	WO/1992/015689	09-17-1992	Charles, et al.		
	23	WO/1999/013053	03-18-1999	Bermudes, et al.		

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OTHER PRIOR ART—NON PATENT LITERATURE DOCUMENTS

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	11	Supplemental Partial European Search Report for Vion Pharmaceuticals, Inc., European App'l No. 00957764.1, Filed May 3, 2002, Dated October 10, 2005	
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	25	Aranda, et al., 1992, "Salmonella Typhimurium activates virulence gene transcription within acidified macrophage phagosomes," Proc. Natl. Acad. Sci USA 89:10079-10083	
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OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS

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	33	Hibbs, et al., 1976, "Role of activated macrophages in nonspecific resistance to neoplasia," J Reticuloendothel Soc 20:223-231	
	34	Hohmann, et al., 1995, "Macrophage-inducible expression of a model antigen in Salmonella typhimurium enhances immunogenicity," Proc Natl Acad Sci U S A 92:2904-8	
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	38	Koshimura, 1961, "On the streptolysin S synthesizing and anticancer activities of cell-free extract from living hemolytic streptococci," Cancer Chemother Rep. 13: 107-111	
	39	Lee, et al., "Identification of a Salmonella typhimurium Invasion Locus by Selection for Hyperinvasive Mutants," Proc. Nta. Acad. Sci. USA, 89: 1847-1851	
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(Use as many sheets as necessary)

Sheet	5	of	6
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Application Number	10/738,423
Filing Date	December 16, 2003
First Named Inventor	KING, et al.
Art Unit	1633
Examiner Name	Qian Janice LI
Attorney Docket Number	873-Z-US

OTHER PRIOR ART—NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	43	North, et al., 1977, "T-cell-mediated concomitant immunity to syngeneic tumors. I. Activated macrophages as the expressors of nonspecific immunity to unrelated tumors and bacterial parasites," J Exp Med 145(2):275-292	
	44	Okamoto, et al., 2002, "Enhancement of anti-tumor immunity by lipoteichoic acid-related molecules isolated from OK-432, a streptococcal agent, in athymic nude mice bearing human salivary adenocarcinoma: role of natural killer cells," Anticancer Res. 22(6A):3229-39	
	45	Okuno, et al., 1990, "Immunomodulating effect of intratumoral (IT) injection of biological response modifiers (BRM) on tumor-bearing hosts," J. Jpn Soc Cancer Ther 25(8):1543-1549. (abstract only)	
	46	Raetz, et al., 1993 "Bacterial endotoxins: extraordinary lipids that activate eucaryotic signal transduction," J Bacteriol. 175(18):5745-53	
	47	Reilly, et al., 1953, "Microbiology and cancer therapy: review," Cancer Res. 13(12):821	
	48	Romick, et al., 1996, "Aerobic and Anaerobic Metabolism of Listeria monocytogenes in Defined Glucose Medium," Applied and Environmental Microbiol 304-307	
	49	Roy, et al., "Mutations in <i>firA</i> , encoding the second acyltransferase in lipopolysaccharide biosynthesis, affect multiple steps in lipopolysaccharide biosynthesis," J Bacteriol. 176(6):1639-46	
	50	Sakamoto, et al., 1986 "Antitumor effect of normal intestinal microflora on Ehrlich ascites tumor Jpn. J. Cancer Res. 79: 109-116	
	51	Simonen, et al., 1993, "Protein secretion in Bacillus species," Microbiological Reviews 57(1):109-137	
	52	Tsujitani, 1998 "Endoscopic intratumoral injection of OK-432 and Langerhans' cells in patients with gastric carcinoma," Cancer 61(9):1749-53	

Examiner Signature	Date Considered
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	53	Youdim, et al., 1977, "Cooperation of immune lymphoid and reticuloendothelial cells during Listeria monocytogenes-mediated tumor immunity," Cancer Res 37(4):991-996	
	54	Youdim, et al., 1976, "Resistance to tumor growth mediated by Listeria monocytogenes. Destruction of experimental malignant melanoma by LM-activated peritoneal and lymphoid cells. J Immunol 116(3):579-584.	
	55	Youdim, et al., 1976, "Resistance to tumor growth mediated by Listeria monocytogenes: collaborative and suppressive macrophage-lymphocyte interactions in vitro," J Immunol 117(5 Pt.2):1860-5	
	56	Youdim, et al., 1974, "Nonspecific Suppression of Tumor Growth by an Immune Reaction to Listeria Monocytogenes," J Natl Cancer Inst 52(1):193-198	
	57	Cunningham, et al., 2001, "A phase I trial of genetically modified Salmonella typhimurium expressing cytosine deaminase (TAPET-CD, VNP20029) administered by intratumoral injection in combination with 5-fluorocytosine for patient with advanced metastatic cancer" Human Gene Ther., 12: 1594-1596	
	58	Dunstan, et al., 1999, "Use of in vivo-regulated promoters to deliver antigens from attenuated Salmonella enterica var. Typhimurium" Infect Immun., 67(10):5133-41	
	59	Elkins, et al., 1994, "In vivo delivery of interleukin-4 by a recombinant vaccinia virus prevents tumor development in mice," Human Gene Ther., 5(7):809-820	
	60	Low, et al., 1998, "Disruption of the Salmonella mshB gene suppresses virulence and TNF-alpha induction yet retains tumor-targeting in vivo," Proc. Amer. Assoc. Cancer Res Annual Meeting, 39: 60 (abst 409)	
	61	Zinkernagel, et al., 1974 "Early appearance of sensitized lymphocytes in mice infected with Listeria monocytogenes," J Immunol, 112(2):496-501	

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